REMARKS

Reconsideration and withdrawal of the rejections set forth in the Final Office Action dated March 31, 2009 are respectfully requested. Claims 1-14, 18-20 and 22-28 are pending. Claims 15-17 and 29 are withdrawn.

I. Administrative Matters

Submitted herewith, and in accordance with 37 C.F.R. § 1.48(c), is a request for correction of inventorship in the instant application. This request is accompanied by a statement from newly added inventor Dr. John W. Shell. The addition of Dr. Shell as an inventor was necessitated by amendment of the claims in Applicant's response dated October 15, 2008. Also enclosed with this response are a declaration signed by the actual inventors and written consent of the assignee. With this correction, the true and correct inventors of the pending claims are Dr. John W. Shell, Jenny Louie-Helm and Dr. Bret Berner.

II. Double-Patenting Rejection

Claims 1, 5 and 11-13 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 17, 21 and 23 of Application Serial No. 10/773,986.

Claims 18-20 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 52 and 65-66 of pending Application Serial No. 10/281,284.

Applicants respectfully note the above-cited applications stand abandoned, thus rendering the rejection moot. However, for the Examiner's convenience, the Notices of Abandonment are attached to this response, and as can be seen the Notice of Abandonment for the 10/773,986 application was mailed November 24, 2008, and the Notice of Abandonment for the 10/281,284 application was mailed January 30, 2009.

In view of these abandoned applications, there is no basis for maintaining the double-patenting rejection. Withdrawal of the rejection is respectfully requested.

III. Rejection Under 35 U.S.C. § 102(a)

Claims 1-13 and 27 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Shell *et al.*, U.S. Publication No. 2001/0018070 (herein "Shell").

This rejection is respectfully traversed.

The present application has an effective priority date of October 25, 2001, less than a year after the publication of Shell, and therefore is not a statutory bar.

Under M.P.E.P. § 715.01(c), "[u]nless it is a statutory bar, a rejection based on a publication may be overcome by a showing that it was published either by applicant himself/herself or on his/her behalf." "Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing ...a declaration... to establish that the article is describing the applicant's own work." A declaration by applicant alone indicating that the applicant is the sole inventor and that the others were merely working under his direction is sufficient to remove the publication as a reference under 35 U.S.C. §102(a) (*In re Katz*, 215 USPQ 14 (CCPA 1982)).

In view of M.P.E.P. § 715.01(c), Applicants hereby enclose a "Katz" declaration by co-inventors John W. Shell and J. Louie-Helm stating they are co-inventors of the claimed subject matter, and that the third co-inventor named in the Shell patent application, M. Markey, was not involved in the aspects of the presently claimed invention.

In view of the foregoing, Applicants submit that the Shell publication represents the co-inventors' own work and does not qualify as work by another under 35 U.S.C. §102(a) or §102(e). Accordingly, withdrawal of this rejection is respectfully requested.

IV. Rejections Under 35 U.S.C. § 103

Claims 1-13 and 22-28 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Shell in view of Hallmark Pharmaceuticals (WO 96/26717; herein "Hallmark '717").

Claims 1-14, 18-20 and 27 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Shell in view of Louie-Helm et al., Proceedings for Controlled Release Society, 2001 (herein, "Louie-Helm") and Cipro® Drug Information Sheet (2000).

These rejections are respectfully traversed.

A1. The Pending Claims

The pending claims are directed to a method for delivering a pharmacologically active agent comprising orally administering to a patient in a fed mode a matrix/active agent tablet dosage form comprised of a polymer matrix and an active agent dispersed in the polymer matrix wherein the dosage form, upon imbibition of water, swells unrestrained dimensionally to a size effective to promote gastric retention and maintains its size for an extended period of time before it is diminished by erosion.

A2. Analysis: Rejection Based on Shell and Hallmark '717

Regarding the rejection based upon the combined disclosures of Shell and Hallmark '717, Shell fails to qualify as prior art under 35 U.S.C. § 102, and therefore cannot be used as a prior art reference in a rejection under 35 U.S.C. § 103. Thus, the rejection based upon Shell and Hallmark '717 cannot stand. Therefore, any rejection of the claims must stand upon Hallmark '717 alone. Applicants contend, the Hallmark '717 lacks sufficiency to sustain an allegation of obviousness.

Hallmark '717 relates to a dosage form designed for a continuous drug release profile as the dosage form travels from the stomach to the small intestine. The dosage form disclosed in Hallmark '717 is comprised of an alginate, a polyacrylate (an enteric polymer), and a gelling polymer, such as hydroxypropylmethylcellulose (HPMC). On page 2, lines 5-6, Hallmark '717 states that "[i]n a low pH environment, alginates and polyacrylates do not swell and/or dissolve properly." On page 2, lines 13-16, Hallmark '717 states that HPMC is a pH independent polymer that will "hydrate at low pH levels to create a viscous gel layer for drug release." Thus, in the low pH environment of the stomach, the alginate and polyacrylate polymers do not swell, and the HPMC polymer at most will hydrate to become a viscous gel. Therefore the dosage form of Hallmark '717, when in the low pH environment of the stomach, cannot and does not "swell unrestrained dimensionally to a size effective to promote gastric retention," as required by Applicants' claimed dosage form in the current methods of treatment.

Moreover, the dosage form of Hallmark '717 is specifically designed to maintain a constant rate of drug release as the dosage form travels through the GI tract, from the low pH of the stomach to the higher pH in the lower GI (see, pages 2-3 of Hallmark '717). In contrast,

Applicants' claimed dosage form administered in the current methods of treatment is specifically gastric retained.

Finally, Hallmark '717 specifically relies on the use of an enteric polymer to increase erosion rates of the dosage form in the small intestine and facilitate drug release in the small intestine. This technical feature would not be applicable to a gastric retained dosage form. The Examiner notes, in the first paragraph on page 12 of the Office Action mailed March 31, 2009, that "Hallmark '717 specifically teaches that at high pH levels, enteric polymers, such as methacrylic acid copolymers, increase erosion rate so as to maintain a constant dissolution rate regardless of the tablet size. So reduction in tablet size does not reduce release rate." In other words, Hallmark '717 teaches the use of a polymer to increase erosion in the small intestine, not in the stomach. Therefore, the inclusion of an enteric polymer, such as methacrylic acid copolymer, to increase erosion rates in order to maintain a constant rate of drug release by a dosage form designed to release drug into the small intestine fails to contribute any elements to a method comprising administration of a gastric retentive dosage form. Accordingly, Hallmark '717 fails to establish a *prima facie* case of obviousness. Withdrawal of the rejection based on Shell and Hallmark '717 is respectfully requested.

A2. Analysis: Rejection Based on Shell in view of Louie-Helm and the Cipro® Drug Information Sheet

As to the rejection based upon the combined disclosures of Shell, Louie-Helm, and the Cipro® Drug Information Sheet, as noted above, Shell fails to qualify as prior art. Moreover, Louie-Helm also fails to qualify as prior art. The Louie-Helm publication was published as abstract no. 6044 in the compilation from the June 2001 28th Annual Meeting of the *Controlled Release Society* held in San Diego California on June 23-28 2001. The abstract was presented on June 26, 2001, as evidenced by the publication of the Table of Contents from the 2001 Proceedings for the 28th International Symposium on Controlled Release of Bioactive Materials (*see* attached document). Thus, this publication was published less than a year before the filing date of the present application, and therefore is not a statutory bar. With reference to the citation from M.P.E.P. §715.01(c) given above, and with reference to M.P.E.P. § 716.10, any rejection based on a publication that is not a statutory bar may be overcome by filing a declaration to establish that the article is describing the

applicant's own work. Thus, accompanying this response is a Declaration by named co-inventors J. Louie-Helm and Bret Berner stating they invented or conceived of the subject matter described in the Louie-Helm publication.

The Cipro® Drug Information Sheet alone fails to support a *prima facie* case of obviousness as it fails to teach or suggest a method of delivering a pharmacologically active agent by orally administering to a patient in a fed mode a matrix/active agent tablet dosage form that swells unrestrained dimensionally to a size effective to promote gastric retention, and maintains its size for an extended period of time before it is diminished by erosion.

Accordingly, the present rejection can not be sustained. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

V. Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

No fees are believed due with this communication. However, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No.:50-4616.

If the Examiner has any questions or believes a telephone conference would expedite the prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-1919.

Respectfully submitted,

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/Susan L. Harlocker/
Susan L. Harlocker
Registration No. 59,144

Correspondence Address:

Customer No. 79975

King & Spalding LLP
P. O. Box 889
Belmont, CA 94002-0889